UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-CV-12257-PBS Hon. Patti B. Saris
THIS DOCUMENT RELATES TO CLASS 1 JURY TRIAL	

DEFENDANT ASTRAZENECA PHARMACEUTICALS LP'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION IN LIMINE TO EXCLUDE THE 2003 OFFICE OF INSPECTOR GENERAL GUIDELINES

Defendant AstraZeneca Pharmaceuticals LP ("AstraZeneca") respectfully submits this memorandum of law in support of its motion *in limine*, pursuant to Rules 402 and 403 of the Federal Rules of Evidence, for an Order excluding Plaintiffs from introducing at trial all documents and testimony relating to the 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) (hereinafter "OIG Guidance"). Plaintiffs recently-filed disclosures include several exhibits related to the OIG Guidance,[1] all of which should be excluded. Defendant AstraZeneca also moves to exclude, on the same basis, all additional documents, testimony, and argument related to the OIG Guidance.

BACKGROUND

The claims at issue in this case involve the pricing and Medicare reimbursement of AstraZeneca's product Zoladex from 1991 until the end of 2003. The OIG Guidance AstraZeneca seeks to exclude was not promulgated until May 5, 2003, eleven and one-half years

[1] See, e.g., Pls.' Exs. 83, 182, 220.

into a twelve-year class period and two years after this suit was filed.[2] It concerns "applicable statutes, regulations, and requirements of the federal health care programs." 68 Fed. Reg. 23731. The OIG Guidance is explicit, however, in recognizing that "pharmaceutical manufacturers should be mindful that many states have fraud and abuse statutes – including false claims, anti-kickback and other statutes – that are not addressed in this guidance." Id. at 23733 n.6.

Nonetheless, in the Class 2 and Class 3 trial, Plaintiffs relied heavily on the contents of the OIG Guidance to support their claim that AstraZeneca's pricing and marketing activities were unfair or deceptive throughout the class period. See, e.g., Trial Tr. 35:25-36:16 (asking witness whether he was aware "that the OIG issued regulations saying that the marketing spread was illegal") (Nov. 28, 2006), 95:06-95:09 ("[T]he guidelines say are just a reflection of what the OIG believes the law has always been.") (Jan. 26, 2007), 98:6-99:25 (claiming that AstraZeneca has "no defense to the OIG Guidelines") (Jan. 26, 2007).[3] Plaintiffs furthermore misleadingly refer the OIG Guidance as the "OIG Guidelines," which implies some sort of rule, as opposed to advice, and have, in fact, stated that the OIG Guidance are "regulations." Trial Tr. 35:25-36:16 (Nov. 28, 2006).

The OIG Guidance itself acknowledges its limited effect.

- "As with previously issued guidances, this compliance program guidance represents the OIG's suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to applicable rules and program requirements. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. The document is intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers." Id. at 23731 (emphasis added).

[2] The OIG first published a solicitation notice seeking input for a proposed compliance program in June, 2001. A draft compliance program guidance was published on October 3, 2002. OIG Guidance, 68 Fed. Reg. at 23731.

[3] See also Pls.' Combined Proposed Findings of Fact, Conclusions of Law and Tr. Br. for the Phase 1 Tr. Against the Track 1 Defs. ¶¶ 390-395, ¶ 403, ¶ 409; Pls.' Post Tr. Br. at 3-4, 7, 9, 12.

- "The identification of a given practice or activity as "suspect" or as an area of "risk" does not mean it is necessarily illegal or unlawful, or that it cannot be properly structured to fit in a safe harbor." Id. at 23734-23735 (emphasis added).

- "Importantly, the identification of a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal in all circumstances or that it may not have a valid or lawful purpose underlying it." Id. at 23731 (emphasis added).

Rather than creating any rules, the OIG Guidance advises pharmaceutical manufacturers about how adequate compliance programs may help prevent investigations into violations of federal health care statutes and regulations. Id. The OIG Guidance covers such topics as forming a compliance committee and a compliance officer, writing compliance standards, and establishing compliance training and a compliance hotline. In describing these components of a compliance program, the OIG Guidance intends to help pharmaceutical manufacturers:

> This compliance guidance is designed to provide assistance to all pharmaceutical manufacturers as they either implement compliance programs or re-assess existing programs. It is the hope and expectation of the OIG that the resulting compliance programs will benefit not only federal health care programs and their beneficiaries, but also pharmaceutical manufacturers themselves.

Id. at 23742 (emphasis added).

ARGUMENT

I. The OIG Guidance Will Be Improperly And Unfairly Used As A Proxy For the Applicable Laws of Multiple Jurisdictions

The Federal Rules of Evidence define relevant evidence as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. The core principle of evidence law which follows is that "evidence which is not relevant is not admissible." Fed. R. Evid. 402. See also Achille Bayart & CIE v. Crowe, 238 F.3d 44, 49 (1st Cir. 2001) (affirming exclusion of memorandum that would not have assisted jury in calculating value of business's assets); Merrill v. County Stores, Inc., 669 F. Supp. 1164, 1169 (D.N.H.

1987). To determine relevance, a court must consider the connection between the evidence sought to be admitted and the elements of the claims made or the defenses offered. Feliciano v. Rullan, 378 F.3d 42, 58-59 (1st Cir. 2004) (affirming court's decision to exclude appellant's proffered evidence where appellant failed to demonstrate how evidence was related to his claim); United States v. Smith, 940 F.2d 710, (1st Cir. 1991) (same).

In this case, Plaintiffs must prove, inter alia, that AstraZeneca made intentional misrepresentations about Zoladex pricing, thereby violating various state consumer protection laws. In re Pharmaceutical Industry Average Wholesale Price Litigation, 230 F.R.D. at 85. Where the OIG has explicitly stated that its intent is to provide assistance to pharmaceutical manufacturers and not to create binding standards, the OIG Guidance is not relevant to determining whether AstraZeneca's conduct was deceptive under 42 state consumer protection laws. Indeed, even as to the federal statutory scheme to which it does pertain, it is simply not authoritative.

The OIG does not have the power to make or interpret rules or regulations. The OIG's inability to promulgate rules flows from the purpose of its office, which is investigatory in nature. See Winters Ranch P'ship v. Viadero, 123 F.3d 327, 333 (5th Cir. 1997) (reversing district court decision, which had been based on the district court's erroneous interpretation of the IG's actions as "regulatory, rather than oversight" in nature, which would have made them unenforceable); see also U.S. Nuclear Regulatory Comm'n v. Fed. Labor Relations Auth., 25 F.3d 229, 232-36 (4th Cir. 1994) (discussing the history and purpose of the office of Inspector General, which is responsible for "conducting and supervising audits and civil and criminal investigations relating to [an] agency's operations"); see also Track 1 Defs.' Joint Mem. in Opp'n to Pls.' Mot. for Partial Summ. J. Against All Track 1 Defs. at 9-11.

In addition, the OIG's interpretation of a rule or regulation is not entitled to legal deference. The Supreme Court has recognized that "interpretations such as those in opinion letters — like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law — do not warrant Chevron-style deference." Christensen v. Harris County, 529 U.S. 576, 586 (2000) (affording Department of Labor's opinion letter only "respect" to the extent it has "the power to persuade" under Skidmore v. Swift & Co., 323 U.S. 134 (1944)) (emphasis added); see also Navarro v. Pfizer Corp., 261 F.3d 90, 99 (1st Cir. 2001) (applying Skidmore standard to determine persuasiveness of EEOC interpretive guidance where the EEOC "never had any authority to promulgate regulations pursuant to the FMLA"). Plaintiffs ignore this fact, and have repeatedly quoted statements where the OIG Guidance imprecisely claims that conduct is "illegal." See, e.g., Trial Tr. 95:06-95:09, 99:8-99:11 (Jan. 26, 2007).

Thus, the OIG Guidance is simply not authoritative on the question of whether AstraZeneca violated the anti-kickback statute, False Claims Act, and other "statutes, regulations and other rules governing Medicare, Medicaid and all other federal health care programs." 68 Fed. Reg. at 23731 n.1. It is, therefore, yet one further step removed from the question in this case — intentional deception under state consumer protection laws.

II. The OIG Guidance Is Too Remote In Time

To win their case, Plaintiffs must prove, inter alia, that AstraZeneca made intentional misrepresentations about Zoladex pricing to consumers from the period of 1991 until the end of 2003.[4] As stated above, the OIG Guidance was not even promulgated until May 5, 2003, two

[4] The Court's class certification order limited Plaintiffs to "only the theory that defendants intentionally made fraudulent misrepresentations of AWP." In re Pharmaceutical Industry Average Wholesale Price Litigation, 230 F.R.D. 61, 85 (D. Mass. 2005).

years after this case was filed. There is no logical connection between any advice contained in the OIG Guidance and AstraZeneca's alleged intent during the almost-twelve years between the start of the class period and the publication of the final OIG Guidance.

It is an accepted proposition that "evidence, though otherwise relevant, may be excluded because it is too remote in space or time from the proposition being proved." Weinstein & Berger, *supra* at § 401.04[2][e] 401-29 (citations omitted); see also Benford v. Richards Medical Co., 792 F.2d 1537 (11th Cir. 1986). In Benford, a case based on the failure of a hip prosthesis, "the relevance of [a] 1981 [safety] standard was in issue because the events material to Benford's claims occurred in the early 1970s." Id. at 1539-40. The Eleventh Circuit upheld the District Court's ultimate decision not to admit the evidence. Id.. Other courts have also excluded government standards that are remote in time from the events at issue. See Fortune Funding, LLC v. Ceridian Corp., 368 F.3d 985, 990 (8th Cir. 2004) (affirming exclusion of evidence regarding the condition of a building from 1997-2000 as irrelevant to proving whether appellee misrepresented the condition of the building in 1985); Nachtscheim v. Beech Aircraft Corp., 847 F.2d 1261, 1275 (7th Cir. 1987) (upholding district court's decision to exclude an FAA bulletin that had been cancelled "almost ten years preceding the manufacture of the plane at issue in this case"); Haynes v. American Motors Corp., 691 F.2d 1268, 1273 (8th Cir. 1982) (finding no error in exclusion of federal regulation that was rescinded before the manufacture of the Jeep at issue). In this case, as in the cases above, a standard announced after the conduct at issue occurred is simply not relevant to determine the legality of that conduct.

To the extent that Plaintiffs argue that the OIG Guidance is merely a statement of existing law that predates its issuance, they should be able to and must be required to demonstrate the governing standards in the absence of reference to the Guidance. Any other result would permit

Plaintiffs to circumvent their burden of proof, and do so in a misleading and unduly prejudicial manner.

II. Admission of the OIG Guidance Would Unfairly Prejudice AstraZeneca

Even under the most generous determination of the relevance of the guidelines — i.e., that they are relevant to the last approximately six months of the class period — such minimal relevance is far outweighed by the risk of confusion and unfair prejudice. Relevant evidence may be excluded under Rule 403 "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Rule 403 "constitutes a tool that a trial judge can use to keep a jury's attention riveted on the dispositive issues." Williams v. Drake, 146 F.3d 44, 47-48 (1st Cir. 1998) (affirming exclusion of guilty plea and other "inflammatory" references), Patten v. Wal-Mart Stores E., Inc., 300 F.3d 21, 27 (1st Cir. 2002) (finding no abuse of discretion where court excluded Maine Human Rights Commission's Finding of Discrimination as more prejudicial than probative).

Here, the danger of jury confusion is palpable. First, a jury may give undue weight to guidance issued by the Office of the Inspector General, failing to comprehend the distinction between such guidance and an administrative rule or legislative statute. Williams, 146 F.3d at 48 ("The procedural and substantive differences between a prison disciplinary board hearing and a jury trial easily could have led to confusion."). The OIG Guidance would similarly encourage the jury to decide against AstraZeneca because of comments made by an office of a regulatory agency, rather than focusing on the proper state consumer protection statutes.

The clear danger of creating jury confusion is illustrated perfectly by the misleading manner in which Plaintiffs characterized the OIG Guidance throughout the Class 2 and 3 bench

trial. For instance, while questioning AstraZeneca witness Alan Milbauer, Plaintiffs engaged in the following exchange:

> Q. And were you aware that the OIG issued regulations saying that the marketing spread was illegal?
>
> MR. WISE: I object to the form of the question.
>
> THE COURT: Overruled.
>
> A. No, I'm not aware. I don't know when they did that.
>
> Q. So while you were at the company, there was no discussion at any time you can recall that, well, maybe we thought it was okay, but now federal authorities are saying it's not okay to market the spread?
>
> THE COURT: Wait. When did the OIG say it was unethical?
>
> MR. BERMAN: 2003.
>
> THE COURT: 2003. So you weren't aware of that before you left?
>
> THE WITNESS: I wasn't aware of that. But I will say, let me respond this way -
>
> MR. BERMAN: There's no question pending, sir.

Trial Tr. 35:25-36:16 (Nov. 28, 2006). In their closing argument, Plaintiffs repeatedly implied that the OIG Guidance creates a legal standard against which AstraZeneca's conduct should be judged. See e.g. Trial Tr. 99:5-99:12 (Jan. 26, 2007) ("The OIG rejected all of these defenses and said, 'No. Purposeful manipulation of the AWP is not appropriate,' and acknowledged that you can't do it . . . they have no defense to the OIG guideline."). Post trial, Plaintiffs have continued to cite the OIG Guidance as establishing a standard of illegality:

> Each of the foregoing actions constitutes unfair acts or practices. First, they fall within the . . . concept of unfairness, particularly given the OIG's admonitions . . . [that] it is illegal for a manufacturer to knowingly establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product.

Id. at 7 (emphasis added). This type of misleading portrayal of the OIG Guidance as law would serve only to confuse the jury.

Second, the OIG Guidance itself is far from crystalline in defining the conduct it discourages. The OIG Guidance states that "importantly, the identification of a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal in all circumstances or that it may not have a valid or lawful purpose underlying it." OIG Guidance 68 Fed. Reg. at 23733. Furthermore, recognizing that "public policy favors open and legitimate price competition in health care," the OIG Guidance refers to the fact that Congress has created an exception to the anti-kickback statute for certain discounts. Id. at 23,735. And in another discussion of pricing, the OIG Guidance states that "where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." Id. at 23733-34. However, the OIG Guidance fails to define "where," exactly, inclusion of such discounts or rebates is "appropriate" in reporting prices.[5]

To demonstrate the legality of its conduct under these contrasting provisions, AstraZeneca would have to expend considerable time explaining the OIG Guidance to the jury. Quick devolution of the trial would likely follow, as the issue would shift from an analysis of state consumer protection laws to a presentation of the federal anti-kickback statute, the False Claims Act, and discounting safe-harbors. Determining whether a discounting or marketing practice would be legal under the relevant federal statutory scheme is outside the scope of the factual issues the jury would properly determine in this case. The lack of clarity of the OIG

[5] AstraZeneca fully and accurately reported all discounts to HCFA/CMS through its regular disclosure of AMP pursuant to the Medicaid regulations.

Guidance would serve to mislead the jury as to the propriety of AstraZeneca's conduct and would encourage the jury to decide the case on an incorrect basis.

Just as they did in the bench trial, Plaintiffs will attempt to use the OIG Guidance to envelop all of AstraZeneca's conduct in a cloud of supposed "illegality" in the jury trial. This improper use of a document that was intended to aid pharmaceutical manufacturers in their compliance programs should not be permitted.

CONCLUSION

For all of the foregoing reasons, this Court should issue an order preventing Plaintiffs from introducing at trial all documents and testimony relating to the 2003 OIG Guidance.

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Dated: March 23, 2007

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered on March 23, 2007 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Katherine B. Schmeckpeper
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